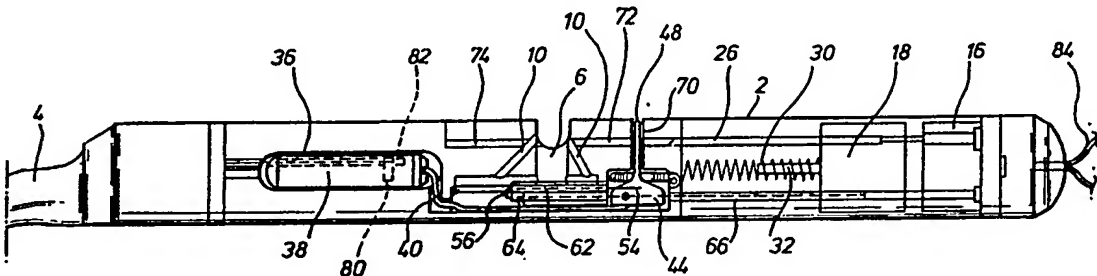




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61B 17/04, 5/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 92/04870 (43) International Publication Date: 2 April 1992 (02.04.92)</p>
<p>(21) International Application Number: PCT/GB91/01630 (22) International Filing Date: 23 September 1991 (23.09.91) (30) Priority data: 9020834.9 25 September 1990 (25.09.90) GB (71) Applicant (for all designated States except US): UNIVERSITY COLLEGE LONDON [GB/GB]; Gower Street, London WC1E 7JE (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): MILLS, Timothy, Noel [GB/GB]; Flat 4, Newman Street, London W1P 3PA (GB). SWAIN, Christopher, Paul [GB/GB]; 52 Gloucester Avenue, London NW1 8JD (GB). BROWN, Geoffrey [GB/GB]; 32 Lea Hall Road, Leyton, London E10 7AN (GB).</p>		<p>(74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, SD, SE, SE (European patent), SN (OAPI patent), SU*, TD (OAPI patent), TG (OAPI patent), US. Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>
<p>(54) Title: SEWING DEVICE</p>  <p>(57) Abstract</p> <p>A sewing device is described for use in surgical procedures inside a patient, which can be used without the need to make an external incision in the patient. The device comprises a slot (6) to which suction is applied at a plurality of locations (12) to suck in a double layer of tissue, and a needle (26) for passing a tag (42) into and through the double layer. The tag (42) may have an article (38) attached thereto, for example a sensor/transmitter.</p>		

+ DESIGNATIONS OF "SU"

Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU ⁺	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TC	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

Sewing Device

This invention relates to a sewing device for use in surgical procedures and, more particularly, relates to a device which can be used inside the body of a patient without the need to make an external incision in the patient, the machine being controlled externally of the patient, for example by endoscopic means. Devices of this general type are described in GB-A-2165559.

An object of the invention is to provide a device for sewing an article to tissue, for example to the lining of the stomach. One example of such an article is a sensor provided with a radio transmitter, for detecting and transmitting to an external receiver information about some parameter relating to the interior of the patient. Another example is an article provided with a slow-release drug for administration to the patient.

Yet another object is to provide a sewing device having improved suction means for holding a double layer of tissue in a slot to enable a stitch to be formed in the tissue.

According to one aspect of the invention there is provided a sewing device for attaching an article to the interior tissue of a patient, which comprises a body provided with means for releasably holding the said article, and a stitching means provided on the body for attaching the said article to the interior tissue of the patient.

Preferably the stitching means inserts a single discrete stitch. The single stitch is preferably in the form of a tag, such tag conveniently

having the general shape of an "I".

According to yet another aspect of the invention there is provided a sewing device comprising suction means for holding a double layer of tissue in a slot, said suction means applying suction to the tissue at a plurality of locations, and means for inserting a stitch into and through the tissue.

The invention is further described below with reference to the accompanying drawings, in which:-

Figure 1 is a plan view of an embodiment of the invention;

Figure 2 is a side elevation of the embodiment;

Figure 3 is a view similar to Figure 1 but showing only a portion of the device, on a larger scale;

Figure 4 is a cross-section taken on line X-X in Figure 3; and

Figures 5, 6 and 7 are views of a portion of the device, on a still larger scale, showing successive steps in its operation.

It should be made clear that although the terms "plan view" and "elevation" are used in the above description of the drawings, these terms are used arbitrarily, and the device is not to be regarded as having any particular orientation which can be said to be its right way up.

The device illustrated comprises a body 2 of a size which enables the device to be introduced into the stomach of an adult patient via the mouth. Thus, for example, the body may be 145 mm in length and 14 mm in diameter. These dimensions are, of course, given only by way of example. The body is shown as being transparent, so that the internal components thereof are visible, and indeed it may be transparent, being

formed of a suitable transparent plastics material. However, it is not an essential requirement that the body should be transparent. The body is attached to an operating device (not shown) via an array of tubes, some of which carry cables, held in a tubular sheath 4. The tubes and cables may be of the order of 1m in length, so that the operating device is external of the patient and a suitable distance away from the patient.

The body is provided intermediate its ends with a cavity 6. The cavity is open to the exterior of the body on one side. One of the tubes within the sheath 4 is connected at its distal end to a source of vacuum, and at its proximal end is connected to a vacuum duct 8 formed within the body 2. The duct 8 communicates with the cavity 6 via an array of ductlets 9 and 10, so arranged that each of the ductlets 10 is open to the cavity 6 at a port 12, there being four ports 12 on each side of the cavity. One side of the cavity can be seen in Figure 4, with its four ports 12. Suction is thus applied to the slot at a plurality of locations.

At its end remote from the sheath 4, the body 2 is hollow and defines a cylindrical chamber 14. Two pistons 16 and 18 are mounted so as to be slidable longitudinally within the chamber 14. The pistons 16 and 18 are connected to the operating device by wires 20 and 22 which can be seen in Figure 4 in a tube 24. The wire 22 is connected to one end of a hollow tube (not shown) the other end of which is connected to the piston 18. The wire 20 passes slidably through the hollow tube and is connected to the piston 16. Thus, the pistons 16 and 18 are movable independently of one another by the wires 20 and 22 respectively.

The piston 18 has one end of a hollow needle 26 secured thereto. The needle 26 has a longitudinal slot 28 which opens into the interior thereof and

extends to the tip of the needle. A compression spring 30 serves to bias the piston 18 towards the distal end of the body, the spring being held in place by having one end thereof surrounding a cylindrical boss 32 which protrudes from the piston 18. The piston 16 carries a cylindrical pushing member 34 which extends into, and is slidable along, the hollow bore of the needle 26.

The body 2 is provided with an elongate, longitudinally extending load cavity 36. The cavity is open towards the exterior of the body and an article which it is desired to attach to the interior of the patient is placed in the cavity. The drawings show a load 38 which may, for example, be a sensor provided with a radio transmitter, for detecting and transmitting to an external receiver information about some parameter relating to the interior of the patient.

It should be noted, however, that the load cavity may be omitted, in which case the sewing device can be used for a pure sewing operation without attaching any article to the tissue.

The article 38 is attached by a flexible cord 40 to a tag 42. This is shown most clearly in Figure 3, where, however, the central portion of the cord is broken away so as not to obscure the underlying components of the device. The tag 42 is generally I-shaped. It has a flat head 44 at one end, a cross-piece 46 at the other end and a connecting member 48 extending between the head 44 and the cross-piece 46. The tag may be made from a suitably inert plastics material, and the connecting member 48 is of sufficiently small diameter to be very flexible. The tag may alternatively be made of some other material, for example an absorbable suture material such as catgut. The tag 42 is used to form the stitch by means of which the device sews the article 38 to the patient,

as will be explained below.

The head 42 is received in a recess 50 formed in the external surface of the body 2. On its base, the recess 50 has a leaf spring 52 which, when the recess is empty, protrudes a certain distance above the base. When the head 42 is pushed into the recess 50 it urges the leaf spring 52 towards the base, and the head is held in the recess by an arm 54 of a U-shaped slider 56. The U-shaped member 56 has a second arm 58, and the arms 54 and 58 are respectively slidable in fixed tubes 62 and 64. The piston 18 carries a rod 66 the lefthand portion of which (as viewed in Figures 1 and 3) is hollow, and the righthand portion of which is not, or is blocked off. The end of the arm 58 is received in the hollow portion of rod 66. When the piston 18 moves leftwardly (as viewed in Figures 1 and 3) the rod 66 moves likewise, and the portion of the rod 66 which is not hollow engages the end of the arm 58 and moves the whole U-shaped member 56 leftwardly. Movement of the piston 18 in the opposite direction leaves the position of the U-shaped member 56 unaffected.

The connecting member 48 of the tag 42 runs in an annular groove 70 formed in the external surface of the body 2. The cross-piece 46 of the tag is received in a longitudinal bore 72 formed within the body, as can be seen most clearly in Figure 5. The bore 72 opens at one end into the cavity 6, and is aligned with a further bore 74 which opens into the cavity on the opposite side. The bores 72 and 74 communicate laterally with the exterior of the body 2 by slots 76 and 78 respectively. These slots are narrower than the diameter of the bores, and the cross piece 46 is of larger diameter than the width of the slots. Thus, once the cross-piece 46 is inserted in the bore 72 it cannot be pulled out of the bore through

the slot 76.

The operation of the device is as follows. Firstly, the cross-piece 46 is inserted into the bore 72 via the cavity 6, and positioned so that the connecting member 48 can be received in the annular recess 70. The cross-piece 46 enters the interior of the needle 26 through the slot 28. The head 44 is then placed in the recess 50 and the U-shaped member 56 is slid manually to the right (as viewed in Figure 3) so that the arm 54 retains it in the recess against the force of the leaf spring 52. The article 38, already attached to the tag 42 by the cord 40, is then placed in the load cavity 36. At this point it should be noted that a leaf spring 80 is provided at the bottom of the load cavity 36, the spring 80 running across the cavity in a recess provided in the base thereof. Before the article 38 is introduced into the load cavity 36 the leaf spring 80 is held down in its recess by moving a rod 82 longitudinally to the right, as viewed in Figure 1 (or longitudinally to the left, as viewed in Figure 2). The rod 82 is connected at its proximal end to a cable (not shown) which runs in one of the tubes in the sheath 4.

With the device now ready for use, it is introduced into the patient, for example introduced into the stomach of a patient via the mouth. To assist in positioning the device correctly, a loop of thread 84, shown in part in each of Figures 1 and 2, may be provided at the forward end of the body. The device may be manipulated via the loop 84 using a pair of forceps introduced into the patient through a catheter.

The body 2 is positioned so that the open face of the cavity 6 is adjacent the tissue to which the article 38 is to be attached. The source of suction is then operated, which causes a U-shaped piece

of tissue to be sucked into the cavity 6, as shown in Figure 6. By applying suction at a plurality of locations the tissue can be held more reliably than by using only a single location as in GB-A-2165559.

Then, as also shown in Figure 6, the hollow needle 26 is moved along the bore 72, across the cavity 6, and into the bore 74, thus passing through both layers of the piece of tissue. The needle is moved by moving the piston 18 to which it is attached. The tag 42 is not moved as a result of movement of the needle, because the diameter of the cross-piece 46 is less than the internal diameter of the needle, and the diameter of the connecting member 48 is less than the width of the slot 28 in the needle.

Moving the piston 18 also has the effect of moving the rod 66, thus causing the U-shaped member 56 to move leftwardly as shown in Figure 3, and so releasing the head 44 of the tag 42 from the recess 50.

At this point, or at some point in the preceding operations, the article 38 is released from the load cavity 36. This is done by moving the rod 82 to disengage it from the leaf spring 80, which is then able to spring away from the base of the load cavity, expelling the article 38.

The piston 16 is then moved leftwardly as shown in Figure 1 (or rightwardly as shown in Figure 2) which causes the pusher rod 36 to move along the hollow needle, engaging the cross-piece 46 and pushing the cross-piece out of the end of the needle. This is as shown in Figure 7. The needle is then withdrawn to its original position, leaving the tag extending through the U-shaped piece of tissue, with the article 38 thereby attached to the tissue via the cord 40. The compression spring 30 helps to reduce the risk of the needle being jammed in the tissue.

It is to be understood that the idea of a

load cavity can be applied not only to devices in which the sewing is effected by inserting a single stitch in the form of a tag, but also to devices, for example, as shown in GB-A-2165559, where a continuous thread is used.

It is further to be noted that the use of a suction cavity in which suction is applied at a plurality of locations (by way of example, eight such locations as in the embodiment described), as opposed to a single location as described in GB-A-2165559, is believed to be novel and inventive in its own right. Accordingly, the present invention is intended to cover all sewing devices (whether using single stitches in the form of tags, or not) and all stapling devices, which employ the use of suction at a plurality of locations whether or not such devices are provided with means for releasably holding an article for attachment to a patient.

Various modifications may of course be made to the device illustrated in the drawings. One such modification is to enable the needle 26 to be changed. Indeed, it may be desirable to use a fresh needle after each use of the device. For this purpose, the needle can be demountably secured to the piston 18, and the slot 78 can be lengthened so that it extends over the full length of the bore 74. At its proximal end, i.e. the end to the righthand side of the cavity 6 as viewed in Figure 5, the slot 78 is only narrower than the bore 74 immediately adjacent the cavity 6, and for the rest is at least of the same width as the bore 74. Thus, to change the needle 26 it can be moved into a position where it lies wholly within the bore 74 and to the right of the narrow portion of the slot 78, and can then be removed through the slot 78 after disconnecting it from the piston 18. To assist in removal, the slot 78 can be provided with a portion of enlarged width to

enable a pair of tweezers to be introduced to grasp the needle.

Another possible modification concerns the means by which the article 38 is expelled from the cavity 36. Rather than relying on a spring for this purpose, the article can be positively expelled by providing the device with an expelling member which replaces the rod 82. The expelling member can be of any convenient shape and is movable between a position in which it allows the article 38 to remain in the cavity and a position in which it forces the article out of the cavity.

Mention should also be made of the fact that although Figures 6 and 7 show the needle 26 passing through two distinct layers of tissue forming the sides of the "U", there may be circumstances where the amount of tissue sucked into the cavity 6 is such that the needle passes only through the base of the "U".

CLAIMS:

1. A sewing device for attaching an article to the interior tissue of a patient, which comprises a body provided with means for releasably holding the said article, and stitching means provided on the body for attaching the said article to the interior tissue of the patient.
2. A device according to claim 1, comprising means for holding a U-shaped double layer of tissue, the stitching means being operable to stitch into and through the tissue so held.
3. A device according to claim 2, which comprises a body, and wherein the means for holding a U-shaped double layer of tissue comprises a slot formed in the body and open to the exterior thereof and means for applying suction to the slot.
4. A device according to claim 3, wherein the suction applying means is effective to apply suction to the slot at a plurality of locations.
5. A device according to any preceding claim, wherein the stitching means is operable to insert a single discrete stitch member.
6. A device according to claim 5, wherein the stitch member is in the form of a tag having a head portion, a cross-piece and a connecting portion connecting the head portion and the cross-piece, and wherein the device has a body adapted to hold the tag thereon.

7. A device according to claim 6, wherein the stitching means comprises an elongate needle movable from a first, rest position to a second position in which at least the tip of the needle passes through the said double layer of tissue, the needle having a longitudinal bore therein which communicates with the exterior of the needle via a longitudinal slot at least over a portion of the needle adjacent the tip, whereby the cross-piece of the tag can be received in the longitudinal bore, the stitching means further comprising a pushing member movable longitudinally within the longitudinal bore to expel the cross-piece therefrom after the tip of the needle has passed through the said tissue.

8. A device according to claim 7, wherein the said body is recessed on the external surface thereof to receive the head and connecting portion of the tag.

9. A device according to claim 8, wherein the head of the tag is retained on the recessed external surface by a retaining member which is movable from a head-retaining position to a head-releasing position.

10. A device according to claim 9, wherein the body is hollow and has a pair of pistons therein which are movable longitudinally independently of one another, one piston carrying the needle and retaining member, and the other piston carrying the pushing member.

11. A device according to any preceding claim, wherein the releasable holding means comprises a cavity formed in the slot and open to the exterior thereof.

12. A device according to claim 11, wherein the

cavity is provided with an expelling means operable to urge the said article out of the cavity.

13. A device according to claim 12, wherein the cavity has a spring member therein, and wherein the device has a spring holding member movable between a first position in which it prevents the spring member urging the said article out of the cavity and a second position in which it permits the spring member to urge the said article out of the cavity.

14. A sewing device for use in surgical procedures, which comprises a body, a slot formed in the body and open to the exterior thereof, means for applying suction to the slot at a plurality of locations, thereby to hold a U-shaped double layer of tissue in the slot, and stitching means for inserting a stitch through the tissue.

Fig.1.

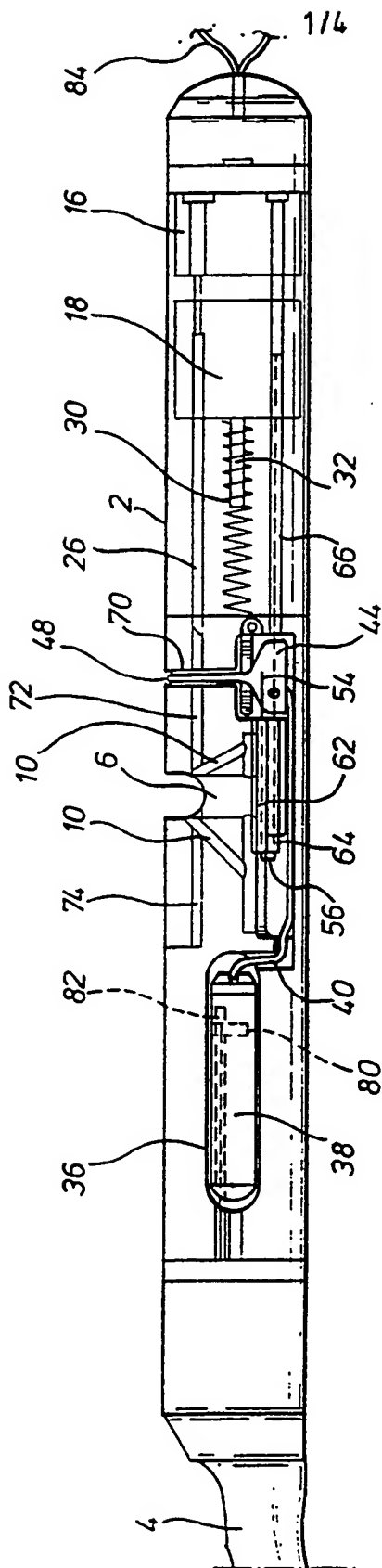
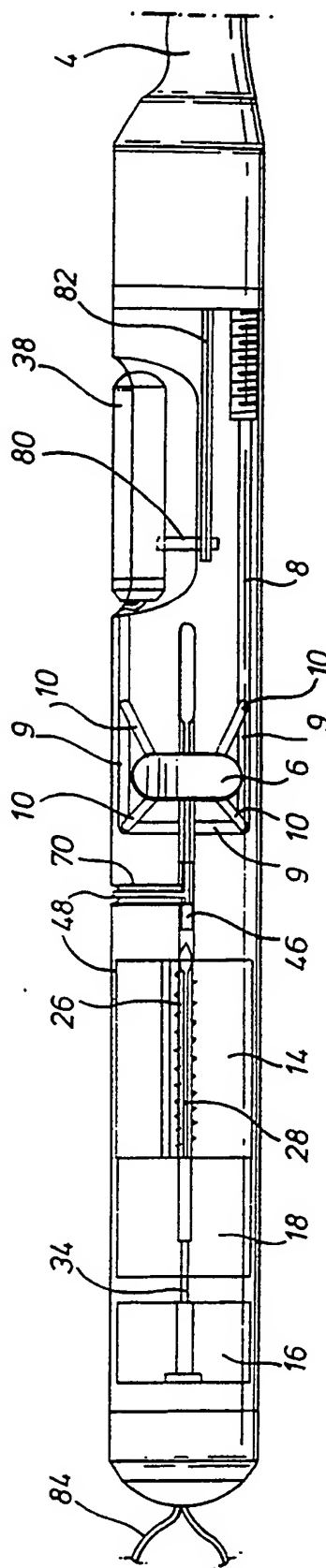


Fig.2.



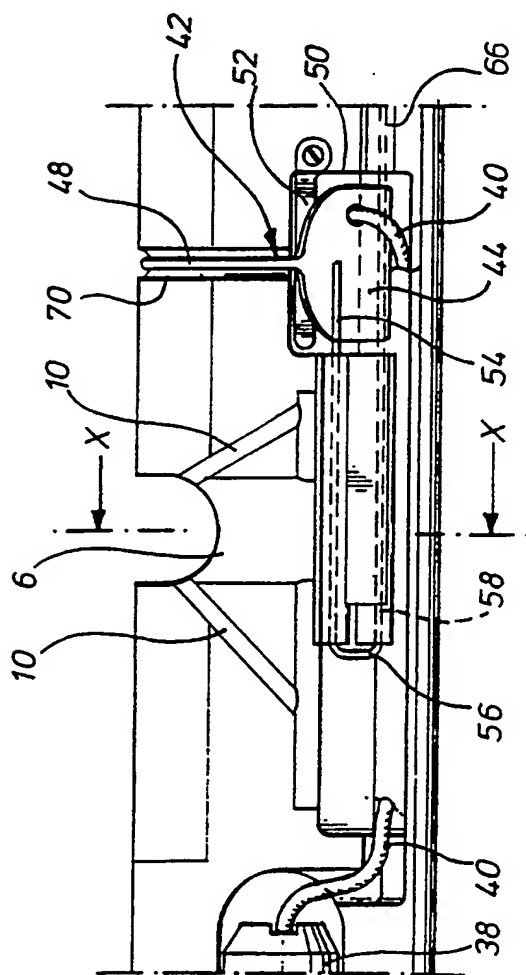


Fig. 3.

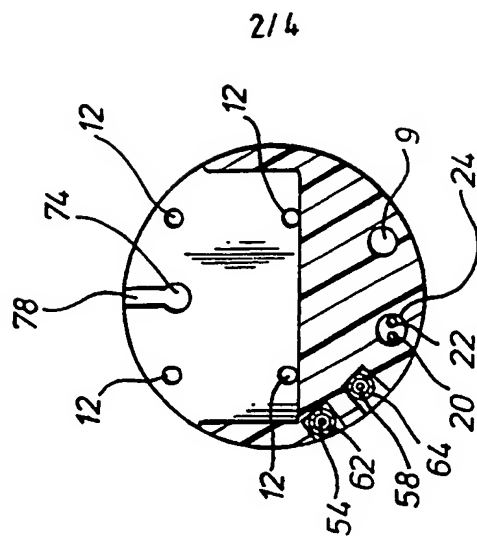


Fig. 4.

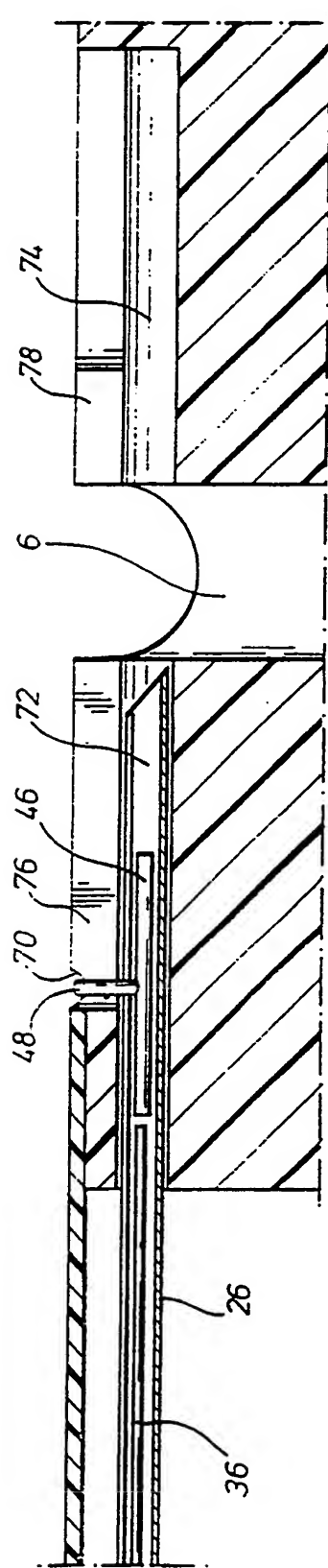


Fig. 5.

3/4

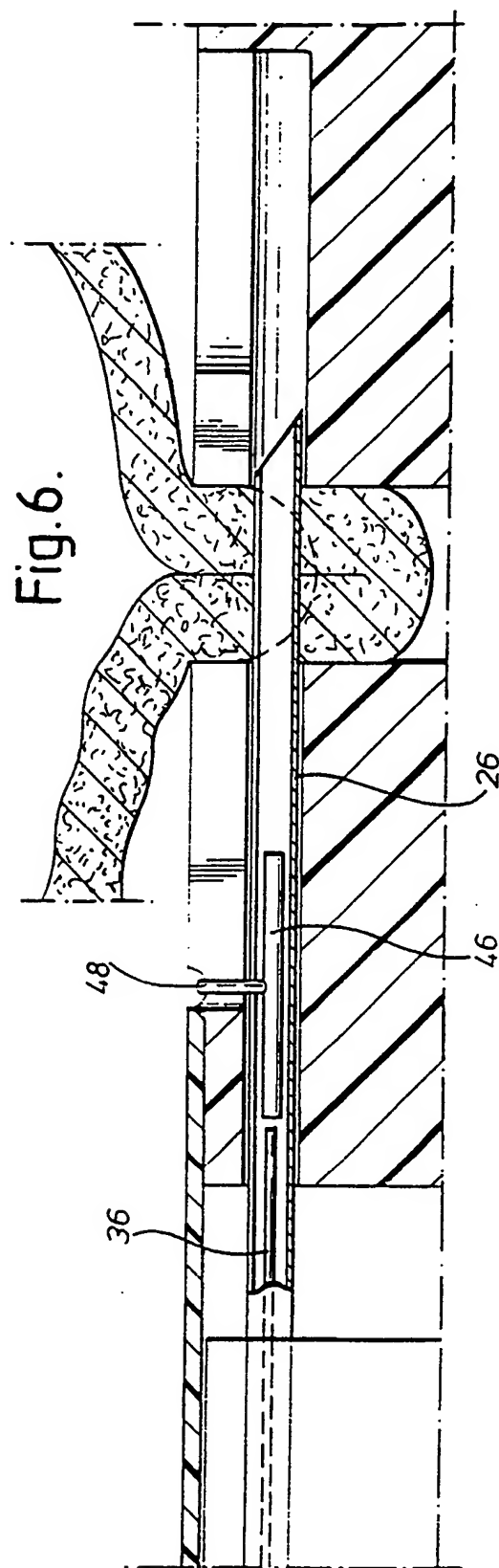


Fig. 6.

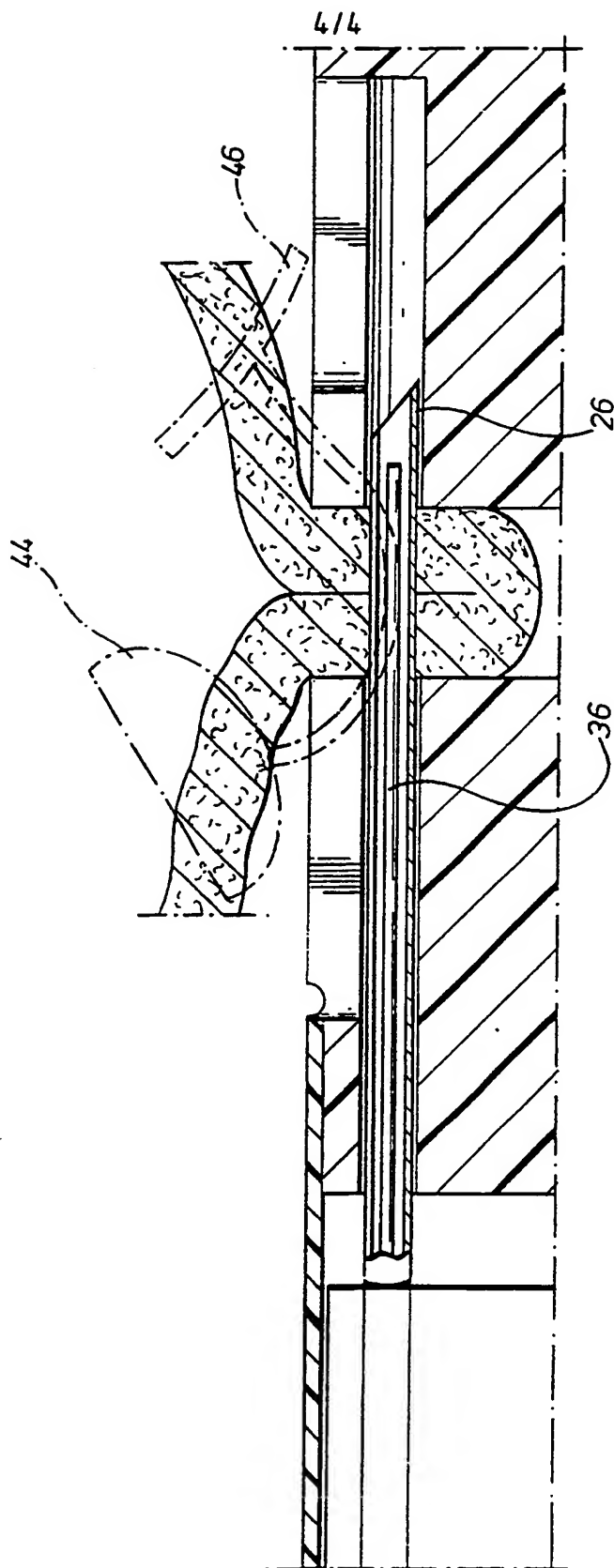


Fig.7.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 91/01630

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)*		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61B17/04; A61B5/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ²		
Classification System	Classification Symbols	
Int.Cl. 5	A61B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ²		
III. DOCUMENTS CONSIDERED TO BE RELEVANT³		
Category ⁴	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claims No. ¹³
Y	EP,A,0 174 843 (UNIVERSITY COLLEGE LONDON) 19 March 1986	1-3,5,14
A	see page 1, line 1 - page 2, line 25 see page 3, line 26 - page 6, line 5 see page 13, line 1 - line 14; figures 1-5 cited in the application	7
Y	US,A,4 306 560 (HARRIS) 22 December 1981 see column 3, line 33 - line 44 see column 5, line 1 - line 3; figures	1-3,5
Y	US,A,3 783 873 (JACOBS) 8 January 1974 see column 7, line 3 - line 9; figures 9,10,15	14
A	US,A,4 696 300 (ANDERSON) 29 September 1987 see abstract; figures 1-5	4
A	US,A,4 235 238 (OGIU) 25 November 1980 see the whole document	6
	---	6,7
	--- -/--	
<p>* Special categories of cited documents : ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
27 NOVEMBER 1991	24. 01. 92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	KLEIN C. <i>C. Klein</i>	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	GB,A,1 249 853 (TAYLOR) 13 October 1971 see figure 1 ---	10
A	WO,A,8 701 270 (ACUFEX) 12 March 1987 ---	
A	WO,A,8 906 513 (BAYLOR) 27 July 1989 ---	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. GB 9101630
SA 51591**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 27/11/91

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0174843	19-03-86	EP-A- 0442588	21-08-91
		GB-A, B 2165559	16-04-86
		GB-A, B 2200072	27-07-88
		JP-A- 61122852	10-06-86
		US-A- 4841888	27-06-89
		US-A- 5037021	06-08-91

US-A-4306560	22-12-81	CA-A- 1135142	09-11-82
		DE-A- 2927143	24-01-80
		FR-A- 2430759	08-02-80
		GB-A, B 2025236	23-01-80
		JP-A- 55032585	07-03-80
		NL-A- 7905336	14-01-80

US-A-3783873	08-01-74	None	

US-A-4696300	29-09-87	US-A- 4736746	12-04-88

US-A-4235238	25-11-80	DE-A, C 2919009	22-11-79

GB-A-1249853	13-10-71	None	

WO-A-8701270	12-03-87	US-A- 4669473	02-06-87
		AU-B- 593582	15-02-90
		CA-A- 1259874	26-09-89
		EP-A- 0236427	16-09-87
		JP-T- 63500702	17-03-88

WO-A-8906513	27-07-89	AU-A- 2943289	11-08-89
		EP-A- 0398932	28-11-90
		JP-T- 3502412	06-06-91
		US-A- 4926875	22-05-90

EPO FORM P479

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.